UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

W. SCOTT HARKONEN,

Defendant.

/

No. C 08-00164 MHP

MEMORANDUM & ORDER

Re: Defendant Harkonen's Motions for a New Trial

On September 29, 2009, a federal jury found defendant W. Scott Harkonen ("Harkonen") guilty of one count of wire fraud, 18 U.S.C. § 1343, and not guilty of one count of felony misbranding, 21 U.S.C. §§ 331(k), 333(a)(2) & 352(a). Now before the court are (1) Harkonen's motion for a new trial due to the government's alleged suppression of exculpatory evidence in contravention of *Brady v. Maryland*, 373 U.S. 83 (1963); and (2) Harkonen's motion for a new trial under Fed. R. Crim. P. 33 on the basis of an *amicus* brief of the United States filed with the U.S. Supreme Court in *Matrixx Initiatives v. Siracusano*, No. 09-1156. Having considered the parties' arguments and submissions, the court enters the following memorandum and order.

BACKGROUND

The court has previously set forth the relevant facts underlying Harkonen's conviction, *see United States v. Harkonen*, 2010 WL 2985257 (N.D. Cal. July 27, 2010) (Patel, J.). The following additional facts are pertinent to the two motions before the court:

I. Veterans Administration (VA) Documents

Prior to trial, the government produced to Harkonen approximately 370,000 documents from a variety of governmental entities, including the FDA, the SEC and the VA. Docket No. 68 at 2. The VA was part of the government team that investigated and prosecuted Harkonen, and the VA has held itself out as a victim of the fraudulent statements at issue in this case. For example, in a press release following the jury's verdict, a VA agent stated:

> [T]oday's verdict . . . demonstrates our commitment to work with our law enforcement partners to aggressively pursue all individuals that would jeopardize the integrity and safety of the VA's health care system. The actions of this defendant served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans. The VA OIG will continue to aggressively pursue investigations of this type and hold those responsible accountable for their actions.

Docket No. 249, Exh. Q. On November 3, 2010 and November 9, 2010, over a year after Harkonen's trial, the government produced 67 pages of VA documents that had not previously been provided to Harkonen. Docket No. 307 (Martins Decl.) Exhs. B & C. According to Harkonen, these internal VA documents show that the statements made in InterMune's August 28, 2002 press release regarding GIPF-001 Phase III trial were not material to physicians. The parties divide such documents into four categories.

The first category consists of three letters from Veterans Integrated Service Network ("VISN") 22,[1] explaining that the relevant clinical data at the time did not support the use of Actimmune to treat IPF. Two letters, bates-stamped VA-000003 and VA-000004 and both dated July 27, 2003, are responses to letters of inquiry from members of Congress regarding why their constituents were unable to receive Actimmune at the VA hospital in Long Beach, CA. In both letters, the VA director stated that "the drug and its use for [the constituent's] condition (Idiopathic Pulmonary Fibrosis), has been extensively reviewed by the VISN Formulary Committee. It has been the VISN Formulary Committee's position that current data does not support the use of this agent outside of clinical trials." No further details are provided in these letters, and neither letter makes any mention of the August 2002 press release. The third letter, bates-stamped VA-000002, is a letter to the son of a VA patient with IPF, similarly explaining that the review committee concluded that

Actimmune should not be prescribed outside clinical trials. This letter does, however, mention the August 2002 press release:

> The medical leadership at the VA San Diego Healthcare System informed that although there have been some preliminary outcomes reported for this medication, the press release you quote from Intermune, the pharmaceutical company, is not believed to be sufficient scientific evidence that this agent is both safe an effective. They further believe that the results of this trial have not undergone any rigorous scientific evaluation for either safety or efficacy

Martins Decl. Exh. B at VA-000002.

The second set of documents consists solely of an October 17, 2002 memorandum from the Chair of the Formulary Subcommittee for VISN-22, indicating that "numerous individuals in the fields of pulmonology, internal medicine, and pharmacology" had "carefully considered" whether to provide Actimmune for a patient with IPF and concluded that "the current evidence is insufficient to warrant the use." Martins Decl. Exh. B at VA-000015. The memorandum continues with an assessment of the preliminary Ziesche study in 1999 and then analyzes and rejects the results of the GIPF-001 Phase III trial, as reported in a September 19, 2002 press release discussing a scientific session held at the European Respiratory Society Annual Congress in Stockholm. It states that "[t]his was the first public release of information on 330 patients who were enrolled in the phase III clinical efficacy study of interferon 1b gamma in IPF." The memorandum makes no mention of the August 2002 press release at issue here, which actually first declared that the trial demonstrated a survival benefit for mild-to-moderate IPF.

The third set of documents consists of guidelines from VISN-9 and VISN-21 indicating when it is appropriate for a VA physician to prescribe Actimmune. Martins Decl. Exh. B at VA-000006-14. The VISN-9 criteria permit VA sites to consider the use of Actimmune for IPF in certain specific circumstances. The document reviews the Ziesche phase II study and indicates that the GIPF-001 phase III study is "underway," indicating that this document antedated the August 2002 press release. *Id*. at VA-000007. The VISN-21 use criteria are dated August 2008, post-dating the August 2002 press release by six years. The criteria prohibit the use of Actimmune to treat IPF based on the GIPF-007 clinical trial results reported in March 2007, which "showed that patients with IPF did not benefit from Actimmune." *Id*. at VA-000010.

The fourth set of documents consists of meeting minutes of the Pharmacology Benefits Medical Advisory Groups ("PBMAGS") for VISN-22 and VISN-9. The VISN-22 meetings took place in September, October and November 2002, and the minutes stated that the PBMAG considered Actimmune "experimental" and not for use in patients unless enrolled in clinical trials. Martins Decl. Ex. B at VA 000019-23, 24-28, 47-51. There is little explanation of how the PBMAG reached these conclusions, and there is no mention of the August 2002 press release. The VISN-9 meetings took place on July 16, 2003 and May 16, 2007. The July 16, 2003 minutes indicated that the PBMAG was "not promoting" the use of Actimmune for IPF but permitted its use "if the patient has exhausted all treatment modalities." *Id.*at VA-000030. The May 16, 2007 minutes indicated that the PBMAG reversed its decision to allow use of Actimmune for IPF apparently based on the negative results of the GIPF-007 clinical trial, announced on March 5, 2007. *Id*. at VA-000042. The August 2002 press release is not mentioned in any of these minutes.

II. *Matrixx Initiatives v. Siracusano*

On November 12, 2010, the United States, through the Department of Justice, the SEC and the DHHS filed a brief with the Supreme Court as *amicus curiae* in *Matrixx Initiatives v. Siracusano*, No. 09-1156. The petitioner in *Matrixx* is a publicly-traded manufacturer of the over-the-counter cold remedy Zicam, and respondents initiated a securities fraud class action against Matrixx on the basis that it failed to publicly disclose information about customers who had lost their sense of smell (a condition referred to as anosmia). Despite being aware of a University of Colorado study revealing that a small number of customers had experienced anosmia, Matrixx continued to market its drug and publicly extolled the growth potential of the company. When the reports of anosmia finally surfaced, Matrixx's stock price fell precipitously.

The district court granted Matrixx's motion to dismiss the complaint, holding that the plaintiffs had not alleged a "statistically significant correlation between the use of Zicam and anosmia so as to make failure to publicly disclose complaints and the University of Colorado study a material omission." *Siracusano v. Matrixx Initiatives*, No. CV 04 0886 PHX MHM, 2005 WL 3970117, at *7 (D. Ariz. Dec. 15, 2005). The Ninth Circuit reversed, observing that there are no

bright-line rules for determining materiality under SEC Rule 10b-5. *See* 585 F.3d 1167 (9th Cir. 2009). The Supreme Court granted certiorari and recently affirmed the Ninth Circuit decision. *Matrixx Initiatives v. Siracusano*, --- S.Ct.---, 2011 WL 977060 (U.S. Mar. 22, 2011).

In it *amicus* brief, the government agreed with the Ninth Circuit's decision and argued that statistical significance is not the only relevant measure of the materiality of the "adverse event" reports of anosmia. *See* Docket No. 322, Exh. A. It argued that "[w]hile statistical significance provides some indications about the validity of a correlation between a product and a harm, a determination that certain data are not statistically significant . . . does not refute an inference of causation." *Id.* at 14. "The observed association may not be statistically significant for reasons other than the lack of causal connection, including sample size and methodology." *Id.* at 15. "More broadly causation can appropriately be inferred through consideration of multiple factors independent of statistical significance." *Id.* The government also stated, in a footnote, that "[t]he same principle applies to studies suggesting that a particular drug is efficacious. A study in which the cure rate for cancer patients who took a drug was twice the cure rate for those who took a placebo could generate meaningful interest even if the results were not statistically significant." *Id.*at 15 n.2. It further observed that "[i]nformation suggesting that a company's product causes harm may be important to an investor even if the information does not establish that the causal link more likely than not exists." *Id*. at 17. Even if the statistically insignificant information does not establish a causal relationship, such information can lead to consumer perception of a risky product, regulatory attention, and product-liability litigation, all of which could materially affect stock prices. *See id.* at 18-21.

The Supreme Court's opinion repeatedly cites to and largely adopts the arguments in the government's *amicus* brief:

> Matrixx's argument rests on the premise that statistical significance is the only reliable indication of causation. This premise is flawed: As the SEC points out, "medical researchers . . . consider multiple factors in assessing causation." Brief for United States as *Amicus Curiae* 12 . . . A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events . . . Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well . . . The contextual inquiry [required under *Basic v. Levinson*, 485 U.S. 224, 236 (1988)]

> may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link.

2011 WL 977060, at *9-11.

LEGAL STADARD

I. *Brady* Violation

"[T]he suppression by the prosecution of evidence favorable to an accused upon request violates due process where the evidence is material either to guilt or punishment, irrespective of the good faith or bad faith of the prosecution." *Brady*, 373 U.S. at 87. A *Brady* violation has three elements: (1) the evidence at issue must be favorable to the accused; (2) the evidence must have been suppressed either willfully or inadvertently by the government; and (3) defendant must have been prejudiced. *See United States v. Kohring*, ---F.3d---, 2011 WL 833263, at *4 (9th Cir. Mar. 11, 2011); *United States v. Williams*, 547 F.3d 1187, 1202 (9th Cir. 2008). Evidence is prejudicial "only if there is a reasonable probability that, had the evidence been disclosed to the defense, the result of the proceeding would have been different." *United States v. Bagley*, 473 U.S. 667, 682 (1985). A "reasonable probability" of prejudice exists when the suppression "undermines confidence in the outcome of the trial." *Kyles v. Whitley*, 514 U.S. 419, 434 (1995). A "reasonable probability" may exist even though the remaining evidence is sufficient to convict. *Jackson v. Brown*, 513 F.3d 1057, 1071 (9th Cir. 2008).

"Suppressed evidence is considered 'collectively, not item by item.'" *Kohring*, 2011 WL 833263, at *5 (quoting *Kyles*, 514 U.S. at 436). Suppressed evidence does not amount to a *Brady* violation if it is "merely cumulative." *Id.* (quoting *Morris v. Ylst*, 447 F.3d 735, 741 (9th Cir. 2006)).

II. Rule 33 Motion

Federal Rule of Criminal Procedure 33 provides that "the court may vacate any judgment and grant a new trial if the interest of justice so requires." Fed. R. Crim. P. 33. In considering a Rule 33 motion, "'[t]he district court need not view the evidence in the light most favorable to the verdict; it

may weigh the evidence and in so doing evaluate for itself the credibility of the witnesses.' " *United States v. A. Lanoy Alston, D.M.D., P.C.*, 974 F.2d 1206, 1211 (9th Cir. 1991) (quoting *United States v. Lincoln*, 630 F.2d 1313, 1319 (8th Cir. 1980)). "'If the court concludes that, despite the abstract sufficiency of the evidence to sustain the verdict, the evidence preponderates sufficiently heavily against the verdict that a serious miscarriage of justice may have occurred, it may set aside the verdict, grant a new trial, and submit the issues for determination by another jury.'" *Id.* at 1212 (quoting *Lincoln*, 630 F.2d at 1319). Such a motion should be granted, however, only "in exceptional circumstances in which the evidence weighs heavily against the verdict." *United States v. Hsieh Hui Mei Chen*, 754 F.2d 817, 821 (9th Cir. 1985) (citing *United States v. Pimentel*, 654 F.2d 538, 545 (9th Cir. 1981)).

DISCUSSION

I. *Brady* Violation

Harkonen argues that the VA documents first produced in November 2010 were suppressed in violation of *Brady*, because they show that the statements made in the August 2002 press release were not material to the decisions of prescribing physicians. Because they show that various VA entities concluded that Actimmune should not be used for IPF without reference to the August 2002 press release and only referred to the data resulting from the clinical trials, the proclamations that Actimmune conferred survival benefits were immaterial.

The government does not appear to contest that it suppressed these documents, either willfully or inadvertently. It does not argue that the VA documents were outside the scope of its document production obligations, nor does it provide any justification or excuse for not providing these documents earlier. Indeed, the government acknowledges that the VA was one of the investigating agencies on this case. Instead, the government focuses exclusively on the remaining two *Brady* elements, namely (1) that the VA documents were not exculpatory and (2) that their suppression was not prejudicial.

For purposes of the wire fraud statute, a statement is material if it has the "natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed." *United States v. Peterson*, 538 F.3d 1064, 1072 (9th Cir. 2008) (quoting *Kungys v. United States*, 485 U.S. 759, 770 (1988)). The "capable of influencing" test is an objective one, which looks at the intrinsic capability of a statement to influence the victim's decision, as opposed to the probabilities of doing so. *Peterson*, 538 F.3d at 1072.

As a preliminary matter, it appears that Harkonen reads the indictment too narrowly with regard to the universe of decision-makers against whom the materiality inquiry should be measured. Paragraph 22 of the indictment alleges that Harkonen knowingly and intentionally devised a scheme to defraud "in order to induce doctors to prescribe, and patients to take, Actimmune to treat IPF." *See* Docket No. 1. Although convincing doctors to prescribe Actimmune was undeniably a central aspect of the alleged scheme, the marketing efforts surrounding the August 2002 press release were not strictly limited to prescribing pulmonologists. *See id*. at ¶ 24 ("It was an essential part of the scheme to defraud that the information in the press release be conveyed to pharmacies that sold Actimmune and to patients and doctors."). The government's theory in the indictment and at trial was that InterMune disseminated the press release broadly to an audience that included doctors, patients and pharmacies. Even if, on the basis of the newly-produced documents, Harkonen could call VA pulmonologists to testify that they looked at the scientific data underlying the press release carefully and disregarded InterMune's interpretation of that data, this would not undermine the materiality of the misrepresentations to the full audience the company tried to influence. Accordingly, to the extent that the misrepresentations had the capacity to influence the decision-making of patients with IPF, such capacity is relevant in analyzing the significance of the suppressed VA documents.

Each of the four categories of VA documents holds very little, if any, exculpatory value for Harkonen, and taken cumulatively the documents fail to cast any serious doubt as to the materiality of the statements at issue here. *See Kohring*, 2011 WL 833263, at *5 ("*Brady*/*Giglio* claims are evaluated collectively, but we must first evaluate the tendency and force of each item of suppressed

evidence and then evaluate its cumulative effect at the end of the discussion" (quoting *Barker v. Fleming*, 423 F.3d 1085, 1094 (9th Cir. 2005)).

The only document that makes any mention of the August 2002 press release is the letter from a VISN-22 director to the son of an IPF patient, in which the VISN-22 director dismisses the press release as support for the efficacy of Actimmune. This letter does at least marginally undermine the conclusion that the press release had the capacity to influence the decision of one doctor. On the other hand, the press release was clearly of some influence on the VA patient and/or his son, who requested that Actimmune be prescribed. The other two VISN-22 letters, to members of Congress, provide no details as to why the extant data fails to demonstrate the efficacy of Actimmune for treating IPF and in no way grapples with the persuasiveness, or lack thereof, of the statements at issue here. Moreover, to the extent that patients went so far as to contact members of Congress in order to obtain Actimmune hints at the persuasive influence of some publicly-available information regarding the drug.

The more detailed memorandum by the Chair of the Formulary Committee of VISN-22 also makes no mention of the August 2002 press release. Instead, it analyzes the results of the Zeische study and the GIPF-001 trial and explains why each is insufficient to establish the efficacy of Actimmune to treat IPF. The memorandum mentions a September 2002 press release from Actimmune and states that this press release was the first disclosure of GIPF-001 trial results, raising an inference that the author was altogether unaware of the earlier August 2002 press release at issue here.

Moreover, although Harkonen repeatedly argues that this memorandum and the similar conclusions expressed throughout these documents indicate a "careful, evidence-based and peer-reviewed medical process in which a pharmaceutical company's initial assessments of efficacy in a press release had no role to play," the analysis in the memorandum appears to buttress the materiality of the misrepresentations made in the August 2002 press release. The author rejects the GIPF-001 as a basis for prescribing Actimmune because the primary endpoint "did not reach statistical significance and, therefore, it cannot be concluded that the agent is safe and effective in

the treatment of IPF." The specific details of the GIPF-001 trial, namely the failure to show statistical significance as to its primary or secondary endpoints, therefore appears to be of great importance to this physician, and it is precisely these details that the August 2002 press release omitted and/or misrepresented. *See Harkonen*, 2010 WL 2985257, at *10 ("[T]he press release never explains the context in which InterMune arrived at the 0.004 p-value for the mild to moderate IPF subgroup. Further, the press release does not explain that the study protocol set out ten secondary endpoints---of which survival time was ranked as only the seventh most clinically relevant---and that all ten failed to produce statistically meaningful results.").

That a press release is not the type of scientific data consulted by physicians in making treatment decisions does not mean that the statements made therein are not material---i.e., that the information conveyed by the press release carries the capacity to affect the relevant decision. The government is not required to show that anyone in fact *relied* upon the statements at issue here in order to show materiality or a wire fraud violation. In *United States v. Jenkins*, 633 F.3d 788 (9th Cir. 2011), defendants were convicted of securities fraud, wire fraud and money laundering related to a "pump and dump" scheme in which defendants falsely promoted a company's prospects in order to artificially inflate the stock price. In challenging the materiality of their false statements, defendants argued "that because the government failed to conclusively prove that any investors were influenced by false press releases to purchase UniDyn stock, the press releases were not material for wire fraud purposes." *Id*. at 802 n.3. The Ninth Circuit rejected this argument, because for a wire fraud violation---as for a securities fraud violation---"[t]here is no requirement that the statements actually influence those to whom they are addressed." *Id*. The court observed that "[i]nformation regarding a company's financial condition is material to investment," and concluded that a "reasonable investor would have wanted to know that UniDyn's allegedly lucrative transactions were shams." *Id*. at 802. Similarly here, even though no physicians may have made treatment decisions in reliance on the press release itself, information regarding the context in which statistical significance purportedly is established is important to the medical community, and the jury heard extensive testimony on this issue. *See Harkonen*, 2010 WL 2985257, at *5-7. The failure to

mention the August 2002 press release in the VISN-22 memorandum at most shows that the author did not rely upon the press release itself; it does not show that the misstatements and omissions contained therein were not material.

The third set of VA documents, the use criteria for VISN-9 and VISN-21, are irrelevant to the materiality of the statements in the August 2002 press release. The VISN-9 criteria appear to predate the conclusion of the GIPF-001 trial, and the VISN-21 criteria postdate the August 2002 press release by six years and appear to rely instead on the GIPF-007 trial results.

The fourth set of VA documents, committee minutes from the VISN-9 and VISN-22 PBMAGs, are also of little, if any, use to Harkonen. The VISN-22 minutes from September, October and November 2002 make no mention of the August 2002 press release, nor do they provide details as to why the PBMAG rejected Actimmune as an IPF treatment. Moreover, they note that the "VISN has experienced increasing instances of patients denied approval of very expensive Non-Formulary drugs at one facility, then trying again at another facility," and specifies "interferon for IPF" as one such drug. Martins Decl. Exh. B at VA-000022. If anything, this document raises an inference that IPF patients in the fall of 2002 were influenced by the misinformation circulating about Actimmune. The VISN-9 minutes from July 2003 again make no mention of the press release and moreover *permit* the prescription of Actimmune for IPF in certain circumstances. The VISN-9 minutes from May 2007 reverse this decision on the basis of the GIPF-007 and therefore have no bearing upon materiality.

Taken cumulatively, the VA documents cast little doubt on the materiality of the misleading statements at issue here. Only a single page makes any mention of the August 2002 press release, and the remaining documents are either largely irrelevant or buttress the natural tendency of the misrepresented GIPF-001 results to affect the decisions of doctors and patients. Moreover, notwithstanding Harkonen's emphasis on the considerable size and influence of the VA within the medical profession, the views represented in the recently-disclosed documents reflect a narrow slice of the VA that objected to the use of Actimmune to treat IPF. It appears that certain VISNs, such as VISN-9, permitted treating physicians to prescribe IPF and only withdrew such permission upon the

termination of the GIPF-007 trial. It is very difficult to conclude, therefore, that the misrepresentations of the earlier clinical trials were incapable of influencing doctors to prescribe, and patients to take, Intermmune for IPF treatment.

Even if there is some minimal exculpatory value to the VA documents, their suppression is hardly prejudicial. Particularly given their negligible weight, the court cannot conclude that there is a "reasonable probability" that the jury would have reached a different verdict had the documents been received in evidence. Firstly, there was extensive evidence introduced at trial from which the jury could infer the materiality of the statements. *See Harkonen*, 2010 WL 2985257, at *10 ("In light of Crager and Fleming's testimony, the jury could have found beyond a reasonable doubt that the sampling context---the use of multiple endpoints and post-hoc, subgroup analysis---was a material fact that was omitted from the press release, and thus, that the press release was false or fraudulent.").[2] InterMune's general counsel testified that the August 2002 press release was the most important press release that the company had issued, and the press release itself touted its own significance, declaring "we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients." Docket No. 331, Exh. J at 3. Materiality was also shown by the extensive, coordinated efforts by InterMune to disseminate the press release to doctors and patients. *See Jenkins*, 633 F.3d at 802-03 (materiality of Internet message board postings demonstrated by testimony that defendant closely monitored the message board and instructed employees to post positive comments and counteract negative ones).

Secondly, there was ample opportunity for Harkonen to pursue an immateriality defense even in the absence of the VA documents. Some of these opportunities were not pursued. While Harkonen was CEO of InterMune, the company commissioned a study of the response of pulmonologists to the press release, indicating that some doctors were cautious to base prescribing decisions on a press release, that some respondents were unimpressed by the lack of statistically significant results, and had a number of questions regarding the assumptions underlying the conclusions drawn in the press release. *See* Docket No. 331, Exh. A. The government produced this

study to Harkonen before trial, but Harkonen did not pursue its findings at trial. Similarly, a poll of practicing pulmonologists regarding the preliminary results of the GIPF-001 study indicated that some doctors failed to find the announced survival benefit to be "compelling" and wanted more information before prescribing Actimmune. *Id*. Exh. B. This poll was included in Harkonen's exhibit list but was not introduced at trial.[3] Furthermore, before trial Harkonen disclosed at least two experts who would "opine that physicians do not make treatment decisions solely on the basis of a press release." Docket No. 331, Exhs. H at 4:18-19; 8:16-17.

The VA documents are therefore, at most, "merely cumulative" of the evidence at Harkonen's disposal to argue immateriality. Harkonen argues that the VA documents are of particularly great weight, because they constitute "an admission of the government" and reveal "the inner workings of one of the largest providers of health professional training in the world." *See* Docket No. 337 at 9. It is unclear, however, what the government is admitting, as the VA documents mention the press release only once, and the generally cursory analyses contained in most of the documents hardly provides meaningful insight into the VA's inner workings. Harkonen had full opportunity to challenge materiality at trial, and the VA documents provide little additional support for this argument.

In light of the substantial evidence of materiality presented at trial, the minimal probative value of the VA documents and their cumulative nature, the suppression of the VA documents does not reasonably undermine confidence in the jury's verdict. Accordingly, Harkonen's motion for a new trial under *Brady* is denied.

II. Rule 33 Motion

Harkonen argues that he is entitled to a new trial on the basis of "newly discovered evidence" in the form of the government's *amicus* brief in *Matrixx*. Because the government in *Matrixx* argued that statistical evidence is not the only reliable indication of causation, it cannot argue here that "statistical principles alone precluded any reasonable conclusion that Actimmune caused the 40 percent relative reduction in deaths among those taking the drug." Docket No. 322 at 14. The government would be forced to admit on the basis of its arguments in *Matrixx* that a determination

of statistical insignificance does not refute an inference of causation. Harkonen cites to a wide range of other criteria, including biological plausibility, the Ziesche study and clinical experience, which, taken together with the GIPF-001 trial, could provide substantial support for inferring a survival benefit for the use of Actimmune as an IPF treatment. *Id*. at 16-19.

The government's *Matrixx* brief does not require a new trial. As a preliminary matter, it is unclear how the brief is "newly discovered evidence." It was filed more than a year after the verdict and contains no factual information of any relevance to Harkonen's conviction. To the extent that the government was monitoring the *Matrixx* litigation at the time of Harkonen's trial, its impressions and developing arguments would clearly be inadmissible attorney work product, not subject to the government's disclosure obligations in the absence of "underlying exculpatory facts." *Kohring*, 2011 WL 833263, at *10. Even in its final form, it is difficult for the court to conclude that this is "evidence" or that it is "new." The government's position and statement in *Matrixx* are argument. Furthermore, Harkonen amply pursued arguments regarding the potential meanings of statistical significance—and debates surrounding p-values more specifically—during cross-examination. *See Harkonen*, 2010 WL 2985257, at *14. Subsequent to the filing of this motion, the Supreme Court issued its opinion in *Matrixx*, agreeing with the government's arguments in its *amicus* brief. The court will therefore determine whether Harkonen is entitled to a new trial in light of the Supreme Court's decision.[4]

Matrixx has little bearing on the issues presented in this case, and to the extent the decision is relevant, it is entirely consistent with the theory pursued by the government. Most obviously, *Matrixx* is a securities fraud class action, Harkonen was prosecuted for wire fraud, and the issues regarding materiality are different. *Matrixx* dealt with whether an investor would view the omitted information regarding anosmia as altering the total mix of information available regarding the company, such that it would affect reasonable investment decisions. The Supreme Court concluded that even though there was no statistically significant data demonstrating a causal link between Zicam and anosmia, reasonable investors may consider the data that did exist to be important. 2011 WL 977060, at *11. Such information could affect both the company's revenues and the riskiness of

the investment, and it stands that an investor reasonably would want to know that a company's main product has been the focus of inquiries into adverse side effects. By contrast, this case involves the coordinated decision-making between doctors and IPF patients to prescribe and take Actimmune, and accordingly the actual existence of a causal relationship between the drug and increased mortality would be of paramount concern. It may certainly be *relevant* to physicians that there is non-statistically significant data showing survival benefits for IPF patients, but as the evidence showed at trial, such data on its own does not *establish* the touted relationship.

Matrixx also directly dealt with reports of adverse events, not with claims of efficacy. Consumers may want to know about even remote medical risks when deciding between various treatments, and accordingly, as observed by the Supreme Court, the FDA requires the disclosure of potential adverse side effects on drug labels even if there is not statistically significant evidence of a causal relationship. *See* 2011 WL 977060, at *10 ("[T]he FDA requires manufacturers of over-the-counter drugs to revise their labeling 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.'" (quoting 21 C.F.R. § 201.80(e))). By contrast, in order to conclude that a drug is safe and effective for a particular use, the FDA requires much more rigorous data establishing a causal relationship. To the extent that the government's *amicus brief* states that "[t]he same principle applies to studies suggesting that a particular drug is efficacious," Docket No. 322 at 15 n.2, all this means is that statistically insignificant data does not negate a causal relationship between a drug and a benefit in the same way that it does not negate a causal relationship between a drug and an adverse event, *see id.* ("[O]veremphasis on statistical significance may cause clinically important differences to be incorrectly denoted as non-significant and ignored." (citation omitted)). It does not mean that statistically insignificant data, on its own, provides a proper basis for substantiating the purported benefits of a drug. Statistically insignificant results "could generate meaningful interest" in the efficacy of a drug for a particular purpose, *id.*, and the testimony at trial indicated that drug researchers often use such results as bases for further exploration, *see Harkonen*, 2010 WL 2985257,

at *6-7 (citing testimony from Drs. Crager and Fleming). The testimony also indicated, however, that such data on its own does not provide the scientifically reliable basis for an efficacy claim.

Harkonen tries to recast the issue in this case as whether there was a good faith reason to believe that Actimmune in fact conferred survival benefits, but the question squarely presented is whether the August 2002 press release misrepresented the results of the GIPF-001 trial in a material way.[5] Statistical significance may not be the end-all and be-all of drug efficacy, but at the same time the testimony at trial demonstrated that statistical significance is still highly relevant. If Harkonen had a good faith basis for concluding that Actimmune was an effective treatment for IPF based on a number of factors outside the GIPF-001 trial results, he could have made those connections in the press release and this would be a very different case. As the court has previously concluded, the false statements at issue here involve misrepresenting the results of the GIPF-001 trial, and the statistical significance of those results is at the heart of the alleged misrepresentation. *See Harkonen*, 2010 WL2985257, at *9-11. The jury heard substantial evidence that the GIPF-001 trial results did not establish the causal relationship announced in the August 2002 press release, that Harkonen knew this, and nothing in *Matrixx* undermines either of these conclusions. Harkonen's Rule 33 motion is therefore denied.

CONCLUSION

For the aforementioned reasons, Harkonen's motions for a new trial are DENIED.

IT IS SO ORDERED.

Dated: April 18, 2011

MARILYN HALL PATEL
United States District Court Judge
Northern District of California

ENDNOTES

1. The VA healthcare system is divided into 21 regions called Veterans Integrated Service Networks, each of which is "responsible for coordination and oversight of all administrative and clinical activities within its specified region of the country." *See* http://www.va.gov/health/MedicalCenters.asp

2. This case is therefore substantially different than *United States v. Goyal*, 629 F.3d 912, 915 (9th Cir. 2010) and *United States v. Beker*, No. 07-0765, Dkt No. 316 (N.D. Cal. Feb. 24, 2011) (Patel, J.), relied on by Harkonen. *See* Docket No. 337 at 8-9. In *Goyal*, the jury had no basis for concluding that an improper accounting method was material to investors as there was no evidence regarding the effects of the accounting method on company revenues. In *Beker*, the indictment alleged that a fraudulent statement would cause the prime contractor to part with money, when the evidence at trial overwhelmingly showed that any loss would be borne by the subcontractor, who was not an alleged victim of the wire fraud scheme.

3. Harkonen did attempt to introduce an investor report indicating that the authors were underwhelmed by the trial data reported in the press release. This report, however, was excluded from trial after the government argued that it related to materiality to investors, who were not charged as victims of the scheme. *See* Docket No. 175.

4. The parties argue over the proper standard of review. Normally the inquiry under Rule 33 is whether new evidence indicates that "a new trial would probably result in an acquittal," *United States v. Harrington*, 410 F.3d 598, 601 (9th Cir. 2005). Harkonen argues, however, that the *Matrixx* brief is "*Brady*-like," requiring a lesser showing that it "could reasonably be taken to put the whole case in such a different light as to undermine confidence in the verdict," *Kyles*, 514 U.S. at 434-35; *see* Docket No. 322 at 13. Although the court seriously doubts that the *Brady* standard applies here, because *Matrixx* in no way undermines the prosecution's theory in this case, the motion is denied under both standards.

5. The government's closing arguments are not to the contrary. Harkonen seizes upon statements by Mr. Gordus such as "the lack of a statistically significant p-value meant that '*you cannot conclude* that Actimmune has a survival benefit'" and "you *can't draw any conclusions* from this trial." Docket No. 353 at 4 (quoting 9/23/09 RT 3568-69 (emphasis added by Harkonen)). Mr. Gordus's remarks make clear, however, that his argument was that the GIPF-001 trial data *on its own* failed to demonstrate the causal relationship set forth in the August 2002 press release. *See, e.g.*, RT 3568-69 ("All of [the testifying doctors] testified that the results of this trial – the results that are in this press release – you cannot conclude that Actimmune has a survival benefit."); RT 3570 ("You can do subgroup analysis on the data once you get it . . . You can [] say to yourself, 'Okay. What looks interesting? Let's look at the data. Let's cut it here. Let's cut it there. Let's see what we can find.' That is just fine. There's nothing wrong with that . . . It's done all the time. Well, what you can't do is take the p-values that you get from that subgroup analysis, and make conclusions based on those p-values. You can't make definitive conclusions about whether a drug works or not based on those p-values."). Moreover, he emphasized that the GIPF-001 trial was not *designed* to test the survival benefit claimed in the press release. *See, e.g.*, RT 3572.